

CLAIMS

1. A ready-to-use vapor hydrated hydrophilic catheter assembly,
comprising:
5 a gas impermeable package containing:
a hydrophilic coated catheter, and
a vapor donating liquid,
wherein the ready-to-use condition of the catheter is due at least
in part to the vapor donating liquid producing a vapor atmosphere within the gas
10 impermeable package that activates at least a portion of the hydrophilic coated
catheter.
2. The catheter assembly of claim 1 wherein the gas impermeable
package has a sealed cavity and the hydrophilic coated catheter and the vapor
15 donating liquid are contained within the sealed cavity.
3. The catheter assembly of claim 2 wherein the gas impermeable
package is formed of a material having an impermeability sufficient for a product
shelf life of between six months and five years.
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4. The catheter assembly of claim 2 wherein the gas impermeable
package is formed of aluminum foil.
5. The catheter assembly of claim 1 wherein the hydrophilic
25 coated catheter comprises a tube having an outer surface with a hydrophilic coating
on at least a portion thereof to be inserted into the urethra.
6. The catheter assembly of claim 5 wherein the hydrophilic
coated catheter further includes drainage eyes formed in the tube near a proximal
30 insertion end thereof and a connector at a distal end thereof.
7. The catheter assembly of claim 6 wherein the connector
comprises a tapered funnel integrally associated with the distal end of the tube for
connection to a device for collecting urine passing through the tube.

8. The catheter assembly of claim 5 including an introducer tip at a proximal insertion end of the tube having slits to define flaps that flex outwardly to form an opening for passing the tube therethrough.

5 9. The catheter assembly of claim 1 wherein the hydrophilic coated catheter includes a tube or shaft and a flexible, collapsible sleeve surrounding the tube or shaft to permit gripping the tube or shaft through the sleeve.

10 10. The catheter assembly of claim 7 including a flexible sleeve formed of a vapor permeable material attached to the tapered funnel and extending so as to cover the proximal insertion end of the tube.

15 11. The catheter assembly of claim 8 including a flexible sleeve formed of a vapor permeable material attached to the introducer tip and extending therefrom substantially to a distal end of the tube.

20 12. The catheter assembly of claim 9 wherein the sleeve is formed of a vapor permeable, liquid impermeable collapsible polymeric film material surrounding the tube or shaft in closely spaced relation.

13. The catheter assembly of claim 9 wherein the sleeve is formed of a material selected from polyethylene, plasticized PVC, polypropylene, polyurethane, and polyethylene oxide block copolymer.

25 14. The catheter assembly of claim 12 wherein the polymeric film material is Medifilm 435 polyethylene oxide block copolymer having a thickness within a range of between 10 and 150 microns.

30 15. The catheter assembly of claim 2 wherein the vapor donating liquid is water comprising no more than 20% of the volume of the sealed cavity of the package.

16. The catheter assembly of claim 15 wherein the water is between 2 and 5ml which comprises no more than 5% of the volume of the sealed cavity in the package.

5 17. The catheter assembly of claim 1 wherein the gas impermeable package has a peripheral seal entirely thereabout and holds a urine collection bag having an introducer tip at one end thereof.

10 18. The catheter assembly of claim 17 wherein the hydrophilic coated catheter is positioned within the urine collection bag with a proximal insertion end thereof adjacent the introducer tip.

15 19. The catheter assembly of claim 5 wherein the tube has a port associated with the proximal insertion end of the tube and a wide thin-walled sleeve covering the tube from end to end.

20 20. The catheter assembly of claim 19 wherein the tube has a funnel integrally associated with a distal end of the tube and the sleeve is sized to receive the funnel as the tube is advanced through the port.

21. A ready-to-use vapor hydrated hydrophilic catheter assembly, comprising:

a gas impermeable package containing:

25 a hydrophilic coated catheter,
a vapor donating liquid, and
a liquid sequestering element,

30 wherein the vapor donating liquid is substantially retained by the liquid sequestering element to minimize the spill hazard, while releasing a vapor to produce a vapor atmosphere within the gas impermeable package, such that the ready-to-use condition of the catheter is due at least in part to the vapor activating at least a portion of the hydrophilic coated catheter, so as to ensure delivery of the hydrophilic coated catheter to the user in a completely ready-to-use condition.

22. The catheter assembly of claim 21 wherein the gas impermeable package has a sealed cavity, the package being formed of a material having a gas impermeability sufficient for a product shelf life in the range of between six months and five years, the hydrophilic coated catheter and the vapor donating liquid being contained within the sealed cavity.

23. The catheter assembly of claim 21 wherein the hydrophilic coated catheter comprises a tube having an outer surface with a hydrophilic coating on at least a portion thereof to be inserted into the urethra including drainage eyes formed in the tube near a proximal insertion end thereof and a tapered funnel integrally associated with a distal end of the tube.

24. The catheter assembly of claim 21 wherein the hydrophilic coated catheter includes a tube or shaft and a flexible, collapsible sleeve surrounding the tube or shaft to permit gripping the tube through the sleeve.

25. The catheter assembly of claim 23 including a flexible sleeve formed of a vapor permeable material attached to the tapered funnel and extending so as to cover the proximal insertion end of the tube.

26. The catheter assembly of claim 23 including a flexible sleeve formed of a vapor permeable material attached to an introducer tip at the proximal insertion end of the tube and extending substantially to a distal end thereof.

27. The catheter assembly of claim 24 wherein the sleeve is formed of a vapor permeable, liquid impermeable collapsible polymeric film material surrounding the tube in closely spaced relation.

28. The catheter assembly of claim 24 wherein the sleeve is formed of a material selected from polyethylene, plasticized PVC, polypropylene, polyurethane, and polyethylene oxide block copolymer.

29. The catheter assembly of claim 27 wherein the polymeric film material is Medifilm 435 polyethylene oxide block copolymer having a thickness within a range of between 10 and 150 microns.

5 30. The catheter assembly of claim 21 wherein the gas impermeable package includes a sealed cavity, the hydrophilic coated catheter, vapor donating liquid and liquid sequestering element are contained within the sealed cavity of the gas impermeable package, the liquid sequestering element comprises a material for absorbing the vapor donating liquid.

10 31. The catheter assembly of claim 30 wherein the material for absorbing the vapor donating liquid is a fabric or foam capable of absorbing substantially all available vapor donating liquid and then releasing a vapor from the vapor donating liquid to produce and maintain a fully saturated vapor atmosphere in a
15 state of equilibrium within the sealed cavity.

20 32. The catheter assembly of claim 31 wherein the hydrophilic coated catheter comprises a tube having an outer surface with a hydrophilic coating on at least a portion thereof and the fabric or foam is substantially coextensive and in alignment with the tube within the sealed cavity to release the vapor in proximity to the tube for uptake by the hydrophilic coating.

25 33. The catheter assembly of claim 32 wherein the fabric or foam is loosely positioned within the sealed cavity and is sized to contain a sufficient quantity of the vapor donating liquid to maintain a fully saturated vapor atmosphere within the sealed cavity in order to ensure continuous hydration of the hydrophilic coated catheter throughout an acceptable product shelf life.

30 34. The catheter assembly of claim 32 wherein the fabric or foam is fixedly positioned within the sealed cavity and is sized to contain a sufficient quantity of the vapor donating liquid to maintain a fully saturated vapor atmosphere within the sealed cavity in order to ensure continuous hydration of the hydrophilic coated catheter throughout an acceptable product shelf life.

35. The catheter assembly of claim 30 wherein the material for absorbing the vapor donating liquid has interstices for holding the vapor donating liquid and releasing a vapor therefrom, and has a surface facing inwardly of the sealed cavity which permits release of the vapor while at the same time preventing the material from sticking to the hydrophilic catheter.

36. The catheter assembly of claim 35 wherein the material comprises a microfiber meltblown fabric having a high capillary draw for the vapor donating liquid and the surface is covered with a material selected from a thin elastomeric hydrogel film, a polymeric netting, and a perforated plastic film.

37. The catheter assembly of claim 35 wherein the material comprises a microfiber meltblown fabric having a high capillary draw for the vapor donating liquid and the surface is treated so as to cause the microfiber meltblown fabric to be liquid wettable with the vapor donating liquid.

38. The catheter assembly of claim 21 wherein the gas impermeable package includes a sealed cavity, the hydrophilic coated catheter, vapor donating liquid and liquid sequestering element are contained within the sealed cavity of the gas impermeable package, the liquid sequestering element comprises a gas permeable pouch containing the vapor donating liquid.

39. The catheter assembly of claim 38 wherein the gas permeable pouch is formed of a liquid impermeable material and is sized to contain a quantity of the vapor donating liquid sufficient to form a fully saturated vapor atmosphere within the sealed cavity in order to ensure continuous hydration of the hydrophilic coated catheter throughout an acceptable product shelf life.

40. The catheter assembly of claim 21 wherein the gas impermeable package has a peripheral seal entirely thereabout and holds a urine collection bag having an introducer tip at one end thereof.

41. The catheter assembly of claim 40 wherein the hydrophilic coated catheter is positioned within the urine collection bag with a proximal insertion end thereof adjacent the introducer tip.

5 42. The catheter assembly of claim 41 wherein the liquid sequestering element is substantially coextensive and in alignment with the tube to release the vapor in proximity to the tube for uptake by the hydrophilic coating

10 43. The catheter assembly of claim 23 wherein the tube has a port associated with the proximal insertion end of the tube and a wide thin-walled sleeve covering the tube from end to end.

15 44. The catheter assembly of claim 43 wherein the sleeve extends from the proximal insertion end of the tube to the tapered funnel and is sized to receive the tapered funnel as the tube is advanced through the port.

 45. The catheter assembly of claim 44 wherein the liquid sequestering element is substantially coextensive and in alignment with the tube to release the vapor in proximity to the tube for uptake by the hydrophilic coating.

46. A ready-to-use vapor hydrated hydrophilic catheter assembly manufactured by a process comprising the steps of:

providing a gas impermeable package having a cavity therein;

placing a hydrophilic coated catheter in the cavity of the

5 package;

placing a vapor donating liquid in the cavity of the package;

sealing the cavity with the catheter and liquid in the package;

and

delaying distribution of the package after sealing the cavity

10 with the catheter and liquid therein for a period of time sufficient:

i) for the vapor donating liquid to produce a vapor atmosphere within the cavity; and

ii) for the vapor atmosphere to complete the activation of the hydrophilic coated catheter by
15 hydrating at least a portion thereof.

47. The catheter assembly of claim 46 wherein the package is formed of a material having a gas impermeability sufficient for a product shelf life in the range of between six months and five years.

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48. The catheter assembly of claim 46 wherein the hydrophilic coated catheter comprises a tube or shaft having an outer surface with a hydrophilic coating on at least a portion thereof to be inserted into the urethra.

25 49. The catheter assembly of claim 48 wherein the tube includes drainage eyes formed near a proximal insertion end thereof and a tapered funnel integrally associated with the distal end thereof.

30 50. The catheter assembly of claim 48 including a flexible, collapsible sleeve surrounding the tube or shaft to permit gripping the tube or shaft through the sleeve to assist in inserting the tube or shaft into the urethra.

51. The catheter assembly of claim 49 including a flexible sleeve formed of a vapor permeable material attached to the tapered funnel and extending so as to cover the proximal insertion end of the tube or shaft.

5 52. The catheter assembly of claim 49 including a flexible sleeve formed of a vapor permeable material attached to an introducer tip at the proximal insertion end of the tube and extending substantially to a distal end thereof.

10 53. The catheter assembly of claim 48 wherein the assembly includes a flexible, collapsible sleeve formed of a vapor permeable, liquid impermeable polymeric film material closely surrounding the tube from end to end.

15 54. The catheter assembly of claim 50 wherein the sleeve is formed of a material selected from polyethylene, plasticized PVC, polypropylene, polyurethane, and polyethylene oxide block copolymer.

20 55. The catheter assembly of claim 50 wherein the polymeric film material of the sleeve is Medifilm 435 polyethylene oxide block copolymer having a thickness within a range of between 10 and 150 microns.

56. The catheter assembly of claim 48 wherein the vapor donating liquid is water comprising no more than 20% of the volume of a tube receiving portion of the sealed cavity of the package.

25 57. The catheter assembly of claim 48 wherein the vapor donating liquid is water of between 2 and 5ml which comprises no more than 5% of the volume of a tube receiving portion of the sealed cavity of the package.

30 58. The catheter assembly of claim 46 where the distribution of the package is delayed for a determinable period of time of between 1 and 45 days to ensure complete vapor hydration of the hydrophilic coated catheter.

59. A ready-to-use vapor hydrated hydrophilic catheter assembly,
comprising:

a gas impermeable package containing:

a hydrophilic coated catheter, and

5 a vapor donating liquid,

such that the vapor donating liquid in the assembly is incapable
of reliably hydrating the hydrophilic coated catheter by direct liquid contact, and
wherein the vapor donating liquid produces a vapor atmosphere within the gas
impermeable package to activate at least a portion of the hydrophilic coated catheter,
10 to ensure delivery of the hydrophilic coated catheter to the user in a completely ready-
to-use condition.

60. The catheter assembly of claim 59 wherein the gas
impermeable package has a sealed cavity, the package being formed of a material
15 having a gas impermeability sufficient for a product shelf life in the range of between
six months and five years, the hydrophilic coated catheter and the vapor donating
liquid being contained within the sealed cavity.

61. The catheter assembly of claim 59 wherein the hydrophilic
20 coated catheter comprises a tube having an outer surface with a hydrophilic coating
on at least a portion thereof to be inserted into the urethra including drainage eyes
formed in the tube near a proximal insertion end thereof and a tapered funnel
integrally associated with the distal end of the tube.

25 62. The catheter assembly of claim 59 wherein the hydrophilic
coated catheter includes a tube or shaft and a flexible, collapsible sleeve surrounding
the tube or shaft to permit gripping the tube or shaft through the sleeve.

30 63. The catheter assembly of claim 62 wherein the sleeve is formed
of a material selected from polyethylene, plasticized PVC, polypropylene,
polyurethane, and polyethylene oxide block copolymer.

64. The catheter assembly of claim 62 wherein the sleeve is formed of Medifilm 435 polyethylene oxide block copolymer having a thickness within a range of between 10 and 150 microns.

5 65. The catheter assembly of claim 60 wherein the vapor donating liquid is water comprising no more than 20% of the volume of the sealed cavity of the package.

10 66. The catheter assembly of claim 60 wherein the vapor donating liquid is water of between 2 and 5ml comprising no more than 5% of the volume of the sealed cavity of the package.

15 67. The catheter assembly of claim 60 including a liquid sequestering element disposed within the sealed cavity of the gas impermeable package for reducing the spill hazard.

20 68. The catheter assembly of claim 67 wherein the liquid sequestering element is a fabric or foam capable of absorbing substantially all the vapor donating liquid and releasing a vapor from the vapor donating liquid to produce and maintain a fully saturated vapor atmosphere in a state of equilibrium within the sealed cavity.

25 69. The catheter assembly of claim 68 wherein the hydrophilic coated catheter comprises a tube having an outer surface with a hydrophilic coating on at least a portion thereof and the fabric or foam is substantially coextensive and in alignment with the tube within the sealed cavity to release the vapor in proximity to the tube for uptake by the hydrophilic coating.

30 70. The catheter assembly of claim 69 wherein the fabric or foam is loosely positioned within the sealed cavity and is sized to contain a sufficient quantity of the vapor donating liquid to maintain a fully saturated vapor atmosphere within the sealed cavity in order to ensure continuous hydration of the hydrophilic coated catheter throughout an acceptable product shelf life.

71. The catheter assembly of claim 69 wherein the fabric or foam is fixedly positioned within the sealed cavity and is sized to contain a sufficient quantity of the vapor donating liquid to maintain a fully saturated vapor atmosphere within the sealed cavity in order to ensure continuous hydration of the hydrophilic coated catheter throughout an acceptable product shelf life.

72. The catheter assembly of claim 67 wherein the liquid sequestering element is formed of a material having interstices for holding the vapor donating liquid and releasing a vapor therefrom, and the material has a surface facing inwardly of the sealed cavity which permits release of the vapor while at the same time preventing the material from sticking to the hydrophilic catheter.

73. The catheter assembly of claim 72 wherein the material comprises a microfiber meltblown fabric having a high capillary draw for the vapor donating liquid and the surface includes a covering selected from a thin elastomeric hydrogel film, a polymeric netting, and a perforated plastic film.

74. The catheter assembly of claim 72 wherein the material comprises a microfiber meltblown fabric having a high capillary draw for the vapor donating liquid and the surface is treated so as to cause the microfiber meltblown fabric to be liquid wettable with a vapor donating liquid.

75. The catheter assembly of claim 67 wherein the liquid sequestering element comprises a gas permeable pouch capable of holding substantially all the vapor donating liquid and releasing a vapor from the vapor donating liquid to produce and maintain a fully saturated vapor atmosphere in a state of equilibrium within the sealed cavity.

76. The catheter assembly of claim 75 wherein the gas permeable pouch is formed of a liquid impermeable material sized to contain sufficient vapor donating liquid to form a fully saturated vapor atmosphere within the sealed cavity to ensure continuous hydration of the hydrophilic coated catheter throughout an acceptable product shelf life.

77. The catheter assembly of claim 59 wherein the gas impermeable package has a peripheral seal entirely thereabout and holds a urine collection bag having an introducer tip at one end thereof.

5 78. The catheter assembly of claim 77 wherein the hydrophilic coated catheter is positioned within the urine collection bag with a proximal insertion end thereof adjacent the introducer tip.

10 79. The catheter assembly of claim 78 wherein the liquid sequestering element is substantially coextensive and in alignment with the tube to release the vapor in proximity to the tube for uptake by the hydrophilic coating

15 80. The catheter assembly of claim 61 wherein the tube has a port associated with the proximal insertion end of the tube and a wide thin walled sleeve covering the tube from end to end.

20 81. The catheter assembly of claim 80 wherein the sleeve extends from the proximal insertion end of the tube to the tapered funnel and is sized to receive the tapered funnel as the tube is advanced through the port.

 82. The catheter assembly of claim 81 including a liquid sequestering element substantially coextensive and in alignment with the tube to release the vapor in proximity to the tube for uptake by the hydrophilic coating.

83. A method of producing a ready-to-use vapor hydrated hydrophilic catheter assembly comprising the steps of:

- providing a gas impermeable package having a cavity therein;
- coating at least a portion of a catheter with a hydrophilic coating;
- placing the hydrophilic coated catheter in the cavity of the package;
- placing a vapor donating liquid in the cavity of the package;
- sealing the cavity with the catheter and liquid in the cavity of the package;
- delaying distribution of the package after sealing the cavity with the catheter and liquid therein for a period of time sufficient:
 - i) for the vapor donating liquid to produce a vapor atmosphere within the cavity; and
 - ii) for the vapor atmosphere to complete the activation of the hydrophilic coated catheter.

84. The catheter assembly production method of claim 83 wherein the package provided is formed of a material having a gas impermeability sufficient for a product shelf life in the range of between six months and five years.

85. The catheter assembly production method of claim 83 wherein the catheter coated with the hydrophilic coating comprises a tube and at least the portion of the tube to be inserted into the urethra is coated with the hydrophilic coating.

86. The catheter assembly production method of claim 85 wherein the tube of the catheter includes drainage eyes formed near a proximal insertion end thereof and a tapered funnel integrally associated with a distal end thereof.

87. The catheter assembly production method of claim 83 wherein the hydrophilic coated catheter includes a tube or shaft and a flexible, collapsible sleeve surrounding the tube or shaft to permit gripping the tube or shaft through the sleeve.

88. The catheter assembly production method of claim 87 wherein the sleeve is formed of a material selected from polyethylene, plasticized PVC, polypropylene, polyurethane, and polyethylene oxide block copolymer.

5 89. The catheter assembly production method of claim 87 wherein the sleeve is formed of Medifilm 435 polyethylene oxide block copolymer having a thickness within a range of between 10 and 150 microns.

10 90. The catheter assembly of claim 83 wherein the vapor donating liquid is water comprising no more than 20% of the volume of the sealed cavity of the package.

15 91. The catheter assembly production method of claim 83 wherein the vapor donating liquid is water of between 2 and 5ml comprising no more than 5% of the volume of a tube receiving portion of the sealed cavity in the package.

20 92. The catheter assembly production method of claim 83 wherein the distribution of the package is delayed for a determinable period of time of between 1 and 45 days to ensure complete vapor hydration of the hydrophilic coated catheter.

93. The catheter assembly production method of claim 83 including the step of placing a liquid sequestering element in the cavity of the package for absorbing the vapor donating liquid and producing a vapor atmosphere therein.

25 94. The catheter assembly production method of claim 93 wherein the liquid sequestering element is substantially coextensive and in alignment with the tube within the cavity to release the vapor in close proximity to the tube.

30 95. The catheter assembly production method of claim 94 wherein the liquid sequestering element is loosely positioned within the cavity and contains enough vapor donating liquid to maintain a fully saturated vapor atmosphere.

96. The catheter assembly production method of claim 94 wherein the liquid sequestering element is fixedly positioned within the sealed cavity and contains enough vapor donating liquid to maintain a fully saturated vapor atmosphere.

5 97. A method for ensuring delivery of a hydrophilic catheter to an end user in a completely ready-to-use condition, comprising the steps of:

providing the hydrophilic catheter within a gas impermeable package together with a vapor donating liquid;

determining the times required for:

10 i) the vapor donating liquid to form a vapor atmosphere in a state of equilibrium within the package; and

ii) the vapor donating liquid to complete the activation of the hydrophilic catheter within the package; and

15 delaying the distribution of the hydrophilic catheter to the end user for at least the longer of the times so determined;

whereby the hydrophilic catheter is in a completely ready-to-use condition when it is delivered to the end user.

20 98. The hydrophilic catheter delivery method of claim 97 wherein the hydrophilic catheter is completely hydrated in the package by the vapor atmosphere that is formed by the vapor donating liquid.

25 99. The hydrophilic catheter delivery method of claim 97 wherein the package provided is formed of a material having a gas impermeability sufficient for a product shelf life in the range of between six months and five years.

100. The hydrophilic catheter delivery method of claim 97 wherein the hydrophilic catheter comprises a tube and a funnel and at least the portion of the tube to be inserted into the urethra is coated with a hydrophilic coating.

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101. The hydrophilic catheter delivery method of claim 100 wherein the tube of the hydrophilic catheter includes drainage eyes formed near a proximal insertion end thereof and a tapered funnel integrally associated with a distal end thereof.

102. The hydrophilic catheter delivery method of claim 97 wherein the hydrophilic catheter comprises a tube or a shaft and includes a flexible, collapsible sleeve surrounding the tube or shaft to permit gripping the tube or shaft through the sleeve.

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103. The hydrophilic catheter delivery method of claim 102 wherein the sleeve is formed of a polymeric material selected from polyethylene, plasticized PVC, polypropylene, polyurethane, and polyethylene oxide block copolymer.

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104. The hydrophilic catheter delivery method of claim 102 wherein the sleeve is formed of Medifilm 435 polyethylene oxide block copolymer having a thickness within a range of between 10 and 150 microns.

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105. The catheter assembly of claim 97 wherein the vapor donating liquid is water comprising no more than 20% of the volume of the sealed cavity of the package.

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106. The hydrophilic catheter delivery method of claim 97 wherein the vapor donating liquid is water of between 2 and 5ml comprising no more than 5% of the volume of a tube receiving portion of the sealed cavity in the package.

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107. The hydrophilic catheter delivery method of claim 97 wherein the distribution of the package is delayed for a determinable period of time of between 1 and 45 days to ensure complete vapor hydration of the hydrophilic coated catheter.

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108. The hydrophilic catheter delivery method of claim 97 including the step of placing a liquid sequestering element in the cavity of the package for absorbing the vapor donating liquid and producing a vapor atmosphere therein.

109. The hydrophilic catheter delivery method of claim 108 wherein the liquid sequestering element is substantially coextensive and in alignment with the tube within the cavity to release the vapor in close proximity to the tube.

110. The hydrophilic catheter delivery method of claim 109 wherein the liquid sequestering element is loosely positioned within the cavity and contains enough vapor donating liquid to maintain a fully saturated vapor atmosphere.

5 111. The hydrophilic catheter delivery method of claim 109 wherein the liquid sequestering element is fixedly positioned within the sealed cavity and contains enough vapor donating liquid to maintain a fully saturated vapor atmosphere.

10 112. A ready-to-use vapor hydrated hydrophilic catheter assembly,
comprising:
a gas impermeable package containing a hydrophilic coated catheter having an introducer tip and a sleeve.

15 113. The catheter assembly of claim 112, wherein the package contains a vapor donating liquid, and wherein the ready-to-use condition of the catheter is due at least in part to the vapor donating liquid producing a vapor atmosphere within the gas impermeable package that activates at least a portion of the hydrophilic coated catheter.